K103598 (1/2)

OCT 17 2011

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# 510(K) SUMMARY
# OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the PROPHECY® Pre-Operative Navigation Alignment Guides.

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|---|---|
| Submitted By: | Wright Medical Technology, Inc.<br>5677 Airline Rd.<br>Arlington, TN 38002 |
| Date: | December 7, 2010 |
| Contact Person: | Sarah Holtgrewe<br><br>Manager, Regulatory Affairs |
| Proprietary Name: | **PROPHECY® Pre-Operative Navigation Alignment Guides** |
| Common Name: | Alignment and Resection Guides |
| Classification Name and Reference: | 21 CFR 888.3565 --Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis--Class II<br><br>21 CFR 888.3560 --Knee joint patellofemorotibial polymer/metal/polymer/semi-constrained cemented prosthesis--Class II |
| Device Product Code and Panel Code: | Orthopedics/87/ MBH, JWH, OOG |
| Predicate Device | PROPHECY® Pre-Operative Navigation Alignment Guides<br>(K093405) |

**headquarters**
**Wright Medical Technology, Inc.** 5677 Airline Road Arlington, TN 38002 **901.867.9971** phone **www.wmt.com**
*international subsidiaries*
**011.32.3.378.39.05** Belgium **905.826.1600** Canada **011.33.1.45.13.24.40** France **011.49.211.862.9990** Germany
**011.39.0250.678.227** Italy **011.81.3.3538.0474** Japan **011.44.1483.721.404** UK

## DEVICE INFORMATION

### A. DEVICE DESCRIPTION

PROPHECY® Pre-Operative Navigation Alignment Guides are patient-specific guides created to fit the contours of the patient's distal femoral and tibial plateau anatomy. The guides are designed and manufactured from patient imaging data (MRI, CT), and are available in two versions: alignment and alignment and resection. The guides are made from biocompatible nylon, and the resection slots are biocompatible stainless steel. The PROPHECY® Guides serve as a alternative to traditional alignment instrumentation used with Wright's ADVANCE® and EVOLUTION™ Total Knee Systems, and thereby reduce the overall number of surgical steps required during total knee arthroplasty. The guides serve to position and align the ADVANCE® or EVOLUTION™ implants in a comparable position to traditional instrumentation.

### B. INTENDED USE

Wright's PROPHECY® Pre-Operative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for use with Wright's ADVANCE® and EVOLUTION™ Total Knee Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for single use only.

### C. PERFORMANCE DATA

The following performance data was used to support the safety and efficacy of the PROPHECY® Pre-Operative Navigation Alignment Guides:

- Cadaver testing by end users analyzing placement location and orientation
- Repeatability testing across design engineers
- Detailed software descriptions and documentation

### D. SUBSTANTIAL EQUIVALENCE INFORMATION

The main difference between the subject and predicate devices is in the addition of the EVOLUTION™ knee system to the indications for use. The safety and efficacy of the PROPHECY® Pre-Operative Navigation Alignment Guides are adequately supported by the substantial equivalence information, materials information, and analysis data provided within this 510(k).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 17 2011

Wright Medical Technology, Inc.
c/o Ms. Sarah Holtgrewe
Regulatory Affairs Project Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K103598
Trade/Device Name: Prophecy Pre-Operative Navigation Alignment Guides
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH, OOG
Dated: September 29, 2011
Received: September 30, 2011

Dear Ms. Holtgrewe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin J. Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K103598

Device Name: PROPHECY® Pre-Operative Navigation Alignment Guides

Indications For Use:

Wright's PROPHECY® Pre-Operative Navigation Alignment Guides are intended to be used as patient-specific surgical instrumentation to assist in the positioning of total knee replacement components intra-operatively and in guiding the marking of bone before cutting. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for use with Wright's ADVANCE® and EVOLUTION™ Total Knee Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY® Pre-Operative Navigation Alignment Guides are intended for single use only.

Prescription Use xxx AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103598